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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,501	08/09/2000	Susan Acton	MNI-132CP3	5106

7590

06/03/2003

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICAL, INC.
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EXAMINER

CHISM, BILLY D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/635,501	ACTON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-17, 45, 47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-7 and 45 is/are allowed.
- 6) ☒ Claim(s) 3-5, 8-17, 47 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Paper No. 11, filed 20 March 2003. After consideration by the Examiner, Claims 8-16, formerly Group III, a fusion protein, in the restriction requirement, have been rejoined with Group II. The restriction is withdrawn between Groups II and III as it is considered that there is no fusion protein. Claims 3-17, 45, 47 and 49-58 are pending and under consideration.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action Paper No. 10 filed 02 December 2002, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. (New) Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of ATCC Designation No. 209510. While the specification provides enough information for one of skill in

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the art to produce a nucleic acid sequence with the same or similar properties as ATCC Designation No. 209510, reproduction of an identical nucleic acid sequence is an unpredictable event. Because it does not appear that ATCC Designation No. 209510 is known and publicly available or can be reproducibly isolated from nature without undue experimentation and because certain of the claims specially require the use of ATCC Designation No. 209510, a suitable deposit of ATCC Designation No. 209510 for patent purposes is required or evidence must be provided that ATCC Designation No. 209510 is well known and readily available to the public.

Furthermore, unless the deposit was made at or before the time of filing, a declaration filed under the 37 C.F.R. 1/132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited ATCC Designation No. 209510 by its depository accession number, establish that the deposited nucleic acid sequence is the same as that described in the specification, and establish that the deposited nucleic acid sequence was in applicant's possession at the time of filing. See In re Lundak, 773 F.2d. 1216, 227 U.S.P.?Q. 90 (Fed. Cir. 1985).

It is not clear from the disclosure that deposits of ATCC Designation No. 209510 meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

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A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. *Identifies declarant.*
2. *States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.*
3. *States that the deposited material has been accorded a specific (recited) accession number.*
4. *States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.*
5. *States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.*
6. *States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.*
7. *Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.*
8. *That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.*

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As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

3. (New) Claims 17 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of claim 47 indicates that the claim is drawn to a genus, i.e. "isolated polypeptides comprising amino acid sequences which are at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2, wherein said polypeptide has at least one bioactivity of an ACE-2 polypeptide".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43

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USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are two species of the claimed genus disclosed that are within the scope of the claimed genus, *i.e.* SEQ ID NOs: 4-5. The disclosure of two disclosed species may provide an adequate written description of a genus when the species disclosed are representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises all isolated polypeptides comprising amino acid sequences which are at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2, wherein said polypeptide has at least one bioactivity of an ACE-2 polypeptide. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

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Claim 17 is rejected for lack of written description for “biological activities.” Under the same reasoning for claim 47 above, the specification does not adequately describe the bioactivities of claim 17.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants’ arguments filed 20 March 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

(Maintained) Claims 17 and 47 remain rejected for the indefinite recitation of the phrase “at least one bioactivity,” wherein it is unclear as to what “at least one bioactivity” would be, i.e. being hydrolyzed by an enzyme is a bioactivity. Applicants argument that the disclosure is adequate and that one of ordinary skill in the art would “clearly comprehend use of the phraseology” is not found persuasive. The amendment is acknowledged, however, the metes and bounds are not defined in the claims or the specification in a way as to clearly indicate the metes and bounds of “at least one bioactivity.”

(New) Claim 47 is indefinite for the recitation of the term “The” beginning the claim. The claim does not make reference to another claim for which the term “The” could pertain. The claim should be amended by both deleting “The” and inserting “An”, or the claim should amend the claim’s dependency to another claim.

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(New) Claim 8 is rejected for the recitation of the indefinite term "at least about", wherein it is unclear whether the claimed sequence identity is at least 90% or about 90%.

(New) Claim 9 is rejected for the recitation of the indefinite term "a bioactivity of an ACE-2 polypeptide." "A" in this phrase can mean any one of many bioactivities of an ACE-2 polypeptide and it is unclear which one bioactivity was intended or if all bioactivities were encompassed by these claims.

Claims 3-4, 10-16 are rejected for depending from rejected claim 8. Claims 49-53 are rejected for depending from rejected claim 47. Claims 54-58 are rejected for depending from rejected claim 17.

Conclusions

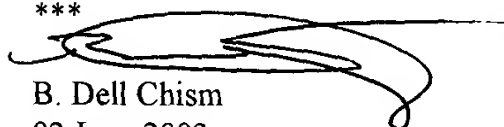
Claims 6-7 and 45 are free of the prior art. Claims 3-5, 8-17, 47 and 49-58 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism
02 June 2003




BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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